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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,569	08/22/2003	J. T. Lin		8217

7590 07/02/2004

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EXAMINER

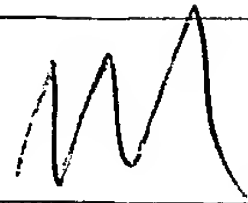
JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,569	Applicant(s) LIN, J. T. 	
	Examiner Henry M Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>082203</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

Some method claims are clearly interpreted without drawings, however, in the instant applicant, drawings are deemed necessary to clearly define the area of the eye being treated and the patterns of laser treatment. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

On page 2, line 10, "the cornea lens loss its" is not proper.

On page 4, line 27, "the fiber tip is easy to break, in which the fiber tip was contacted to the scleral" is improper wording.

On page 5, line 16, the word "present" is not clear. The examiner believes it was intended to be prevent.

On page 6, first paragraph, this text is a repeat of the text on page 5 lines 25-36.

On page 7, line 24, "without open it as a flap" is unclear.

On page 8, line 25, "are 45 degree mounted" is unclear.

The sentence ending on page 9, line 23 is an incomplete sentence.

Claim Objections

Claims 2, 5, 6 and 8 are objected to because of the following informalities: cited ranges are enclosed in parenthesis. Parenthesis are not commonly used in this manner making the exact intention unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 cites "selecting a beam spot controller mechanism focus said laser beam to an articulated arm". The meaning is unclear, perhaps due to missing words.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,263,879 to Lin. The '879 patent discloses a method for treating presbyopia by ablating scleral tissue in the area of the zonule fibers (outside the limbus) to increase vision accommodation (Col. 5, lines 1-5) using an excimer laser at a wavelength of 193 nm (Col. 4, line 11), the ablation beam being controlled to spot size of from 0.1 to 0.8 mm and scanned in a pattern (Col. 2, line 67) and that may use an articulated arm (Col. 4, line 41) controlled manually

Art Unit: 3739

(by a surgeon) for delivery of the ablative beam. The pulse energy is disclosed as between 0.1 and 5.0 mJ (Col. 4, line 21). The focusing lens (Fig. 1, # 3) is interpreted as a spherical lens.

Regarding claim 10, the ablation is performed between two circles having diameters of about 8-11 mm and 12-15 mm (Col. 5, lines 5-6).

Regarding claim 11, the patterns are disclosed as radial lines, curved lines or spots (Figs. 4A-4D).

Regarding claims 12 and 13, the treatment parameters would be expected to yield the specified accommodating reactions in any eye.

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2001/0029363 to Lin. The '363 patent application discloses a method for treating presbyopia by ablating scleral tissue in the area outside the limbus (Paragraph 0031) to increase vision accommodation using an excimer laser at a wavelength of 193 nm (Paragraph 0036), the ablation beam being controlled to spot size of from 0.1 to 2.0 mm and scanned in a pattern (Paragraph 0033) that may use an articulated arm (Paragraph 0037) for delivery of the ablative beam. The laser is used to remove the scleral tissue and may be used to remove the conjunctiva (Paragraph 0032).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,263,879 to Lin. The '879 patent is discussed above, but does not disclose specifics of the articulated arm. Articulated arms for laser delivery are common in the art. At the time the

Art Unit: 3739

invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide an articulated arm with a sufficient number of joints and mirrors to yield the maneuverability required and most efficient energy delivery to the treatment site because Applicant has not disclosed that a specific arm configuration or mirror mounting means provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any number of arms and joints that provided the radiation required for treatment because treatment is dependent on the dosage. Therefore, it would have been an obvious matter of design choice to configure the articulated arm of the '879 patent to obtain the invention as specified in claims 5 and 6. Examples of such arms are U.S. Patent 5,112,328 to Todoada et al. and U.S. Patent 5,549,632 to Lai.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,263,879 to Lin as applied to claim 5 above and further in view of U.S. Patent 5,112,328 to Todoada et al. The '879 patent is discussed above, but does not disclose ablation via direct contact with an eye or a detachable contact piece. The '328 patent discloses contact treatment of an eye with a laser (Fig. 11). It is intuitive that parts of such instruments that contact a patient must be sterilized or discarded after use. The tip (Fig. 11, # 65) is interpreted as detachable for such purpose. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the detachable tip as taught by the '328 patent in the invention of the '879 patent as it represents common sense medical precautions.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,263,879 to Lin as applied to claim 5 above and further in view of U.S. Patent 5,112,328 to Todoada et al. and further in view of U.S. Patent 6,745,775 to Lin. The '879 and '328 patents are discussed above, but do not teach the depth of ablation of the scleral tissue. The '775

Art Unit: 3739

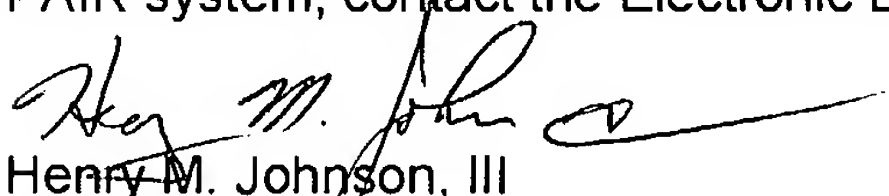
patent discloses the depth required in the treatment of presbyopia to be 60-90% of the scleral tissue, which is typically 500-700 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the depth of ablation as taught by the '775 patent in the '879 patent as modified by the '328 patent to achieve the accommodation desired.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Patent Examiner
Art Unit 3739